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FOLEY AN SUITE 500	ND LARI	ONER	SAKELARIS	, SALLY A	
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Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)					
	09/782,604	GOSWAMI ET AL.					
Office Action Summary	Examiner	Art Unit					
	Sally A Sakelaris	1634					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status							
1)⊠ Responsive to communication(s) filed on <u>12 N</u>	ovember 2003.						
	<u> </u>						
3) Since this application is in condition for allowa	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims							
 4) Claim(s) 1-107 is/are pending in the application. 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1-4,8,11,28,32,33,46,52,58,60-66,69,71,82 and 83 is/are rejected. 7) Claim(s) 62 and 76 is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. 							
Application Papers							
9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. §§ 119 and 120							
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some color None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78. a) The translation of the foreign language provisional application has been received. 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78. 							
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) D Notice of Informal F	(PTO-413) Paper No(s) Patent Application (PTO-152) E. A LIGNMENT					

Continuation of Disposition of Claims: Claims withdrawn from consideration are 5-7,9,10,12-27,29-31,34-45,47-51,53-57,59,67,68,70,72-75,77-81 and 84-107.

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DETAILED ACTION

This action is written in response to applicant's correspondence submitted 11/12/2003. Claims 1-4, 8, 11, 28, 32-33, 46, 52, 58, 60-66, 69, 71, 76 and 82-83 have been amended, no claims have been canceled, and no claims have been added. Claims 1-107 are pending, with 5-7,9,10,12-27,29-31,34-45,47-51,53-57,59,67,68,70,72-75,77-81,84, 85 and 86-107 directed to non-elected subject matter and as a result withdrawn from consideration. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as necessitated by applicant's amendments to the claims. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is Non-FINAL**.

Claim Objections

2. Claim 62 is objected to as the recitation of "coloniesu" is assumed to be a typographical error that requires amelioration. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3, 4, 32, 33, 46, 52, 58, 82 and 83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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A. Claim 3, 4, 32, 33, 46, 52, 58, 82 and 83 are indefinite over the recitation of "control gene region". This phrase makes the claims unclear because the specification does not define what is encompassed by "control gene region". There is no fixed definition in the art for what constitutes a control gene region. It is unclear, eg. whether the term refers to the regions potential to control every gene, whether it is a region of genes that are in some way controlled by their surroundings, whether selection pressures control this region, or whether there is a specific sequence with which this title of "control gene region" corresponds. The claims should be amended to clarify to what specific position "control gene region" refers.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 1-4, 8, 28, 46, 52, 58, 60-66, 69, and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foran(J. of Exp. Zoology, 1991) in view of Yamaguchi et al.(Molecular Phylogenetics and Evolution, 2000) in further view of Davidson(WO 92/05277), in even further view of Lee et al(J Mol. Evol. 1995), in even further view of Herrnstadt et al.(US Patent 5,827,657) and in an even further view of Haygood et al.(J. of Exp. Zoology, 1994).

Foran teaches construction of bacterial and Myctophid fish clones to be used as probes.

The reference teaches with respect to claim 1: (i) extracting the DNA from the muscle tissue of a myctophid fish, (ix) ligating the Vibrio fischeri Lux clone pJE205, following digestion into

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Bluescript vector DNA using published protocols(Foran, 2), (xi) and (xii) The reference further teaches that "the ligation mixture was used to transform competent E. coli cells (XL1-blue, Stratagene)"(Foran, 2) and that "plasmid DNAs from transformed bacteria were isolated by the alkaline lysis method"(Foran, 2). Lastly the reference teaches that "in a similar manner, fragments of fish DNA were cloned for use as positive controls and to help quantitate the relative amount of DNA in a given lane on fish blots"(Foran, 2). It should be noted that included in the reference's teaching of the Bluescript vector DNA(Stratagene Cloning Systems) is the further teaching of the embodiments of claims 60-65, all relating to said system.

Foran does not teach claim 1's steps relating to amplification and cloning included in (ii)-(viii), (x), (xiv)-(xxiv), nor does it teach the method wherein the myctophid fish is from Stenobrachis leucopsarus, or the method wherein the gene regions to be amplified from this fish are mitochondrial in source.

Yamaguchi et al. teach generically, molecular phylogeny and larval morphological diversity of the lanternfish genus Hygophum (Teleostei: Myctophidae)

With respect to claim 1: (i)extracting the DNA from the muscle tissue of a myctophid, of the order Teleostei, fish(Pg. 104), (ii) selecting gene regions in the extracted DNA with the selected primers and the amplifying the same using polymerase chain reaction (PCR), (iii) eluting the PCR amplified DNA(bottom right Pg. 104), (v) cycle sequencing of eluted DNA through use of the Applied Biosystems 373 DNA sequencer, (viii) confirming the sequences for the target gene through alignment programs such as CLUSTAL X and analyzing phylogenetic relationships using maximum-parsimony (MP), maximum-likelihood (ML), and neighborjoining (NJ) methods(Pg. 105).

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With respect to claim 3: Yamaguchi teaches the method above wherein the DNA from the muscle tissue is mitochondrial(Pg. 104).

With respect to claim 28, Yamaguchi teaches the method above wherein the cycle sequencing primer concentration used was 2.5µl(Pg. 104).

Davidson et al. teach: With respect to claim 1: (i) extracting samples of skeletal muscle from different tuna species(Pg. 43) (ii) selecting the gene regions in the extracted DNA with the selected primers and the amplifying the same using polymerase chain reaction (PCR)(Pg. 45) (iii) eluting the PCR amplified DNA by centrifugal dialysis(Pg. 46) (iv)reamplifying the gene regions from PCR amplified DNA and eluting the same(Pg. 47, lines 24-30(2nd PCR) lines 33-Pg. 48 line 4(Eluting)) (v) cycle sequencing the eluted DNA using a single primer(Pg. 49, Ex.1) (vi) purifying extension products through use of DNA Sequencing kit(Pg. 50) (vii) sequencing the extension products on an acrylamide gel(Pg. 50, lines 9-10) (viii)confirming the sequences for the target gene by comparing it to sequences from known species(50), (xxiv) designing species specific primers from the sequences(abstract).

With respect to claim 3: Davidson et al. teach the method above wherein the DNA from the muscle tissue is mitochondrial in source(Pg. 46).

Lee et al. teach: With respect to claim 1: (i)-(viii) total genomic DNA was prepared from muscle tissue of a teleost fish, followed by multiple steps of PCR amplification with primers specific to the mitochondrial control region, specifically, the D-loop region(Pg. 55 *Amplification*), (ix) ligating the eluted PCR product, of an amplified D-loop region from genomic DNA of a teleost fish's muscle tissue(Pg. 55), in a vector, a pBluescript II plasmid and subsequent transformation of ligated plasmid and plating methods followed the

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manufacturer's (Stratagene) instruction manual, (x)-(xxxiv) are taught inherently in the references teaching on page 55 of the standard miniprep analysis (Sambrook et al. 1989) and furthermore through their teachings of sequencing and sequence analysis of the miniprepped DNA.

With respect to claim 4, Lee et al. teach the above method wherein the mitochondrial genes amplified belong to the D-loop gene region of fish in the order, Teleost(of which Myctophidae is a member)(Entire document).

Herrnstadt et al. teach collectively, the direct cloning of PCR amplified nucleic acids.

With respect to claim 1: (ix) ligating the eluted PCR products in a vector(Col. 12) (x) preparing the electro-competent cells for electro transformation(Col. 15) (xi) electro transforming the host cells(Col. 15) (xii) growing and harvesting of transformed host cells(Col. 16) (xiv) confirming that the transformed bacteria has the plasmids with the gene inserts by PCR(Col. 19) (xv) purifying recombinant plasmid DNA having the cloned gene probes from the transformed host cells(Col. 19) (xvi)checking purity and specificity of the cloned DNA probe insert by cutting with restriction enzyme(Col. 19) (xvii) confirming the molecular size of the DNA probe insert(Col. 19).

Haygood et al. teaches: With respect to claims 1 and 2: the isolation of genomic DNAs from muscle of the Lanternfish genus, specifically hybridization of gene probes to DNA from muscle and skin of myctophids, namely Stenobrachius leucopsarus(Table 1 and Pg. 227 right side) is taught. Probes are hybridized to the DNA isolated from muscle tissue of Stenobrachius leucopsarus to establish that bioluminescence of Myctophid and Stomiiform fishes is not due to bacterial luciferase.

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Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the reference of Foran in view of Yamaguchi to analyze the mitochondrial gene of Myctophids since "the genus taught, hygophum is one of 32 genera in the family myctophidae" and as a result will yield similar results to that expected from another species, S. leucoparus. In addition, it would have been obvious to incorporate Blast email in the method of Foran in view of Yamaguchi as it is seen as an equivalent technology to the methods Yamaguchi et al. taught of sequence alignment. It would have also been obvious to alter the concentration of the cycle sequencing primer concentration from 2.5 µl to 2.0 µl, as optimization of PCR is a skill well known in the art. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the reference of Foran in view of Yamaguchi in further view of Davidson to include the steps of claim 1, that although are well known in the art, were not taught by Foran and Yamaguchi but whose combination is motivated by the reference's teaching of a more complete amplification process and cloning regiment for extracted genomic DNA from the muscle tissue of another related fish. It would have also been obvious to repeat the steps (xviii)-(xxiii) including PCR amplification, sequencing and blast emailing as the reference and knowledge in the art, previously taught the use of these steps and their repetition does not make them novel. Davidson et al. also provides the motivation of incorporating their method steps as the ability to probe genetic material, "as well as manipulate genetic material, has increased the need for means to analyze the composition and base order of genetic material...It is therefore desirable to provide for recording various genetic fragments which allow for hybridization with the complementary fragment, so that mixtures may be analyzed for the particular nucleotide sequences" (Pg.8). It would have been

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prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the reference of Foran in view of Yamaguchi in further view of Davidson and in even further view of Lee to have included the amplification of a teleost fish, mitochondrial, D-loop control region as "recently the use of nucleotide sequence data rather than RFLPs, has been encouraged, primarily because of the greater sensitivity of sequencing in detecting variants" and furthermore that "PCR techniques make it feasible to target particular gene segments carrying the highest density of intraspecific variation in large numbers of individuals" (Lee, 54). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the reference of Foran in view of Yamaguchi in further view of Davidson and in even further view of Lee and in an even further view of Herrnstadt et al. as the methods described in the reference for the expected benefit that "sequence information obtained by the present invention will be more reliable than previously available from direct sequencing of PCR amplification products due to more specific ligation reactions and reduced numbers of restriction fragments" (Col. 3). Lastly, It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the reference of Foran in view of Yamaguchi in further view of Davidson and in even further view of Lee and in an even further view of Herrnstadt et al. and in an even further view of Haygood as the reference's teaching of probes to Stenobrachius leucopsarus is an addition to the teachings of Foran who also taught this same method but only to other myctophidae, not to the specifically claimed genus and species of Stenobrachius leucopsarus. As a result, combining the teachings of Foran in view of Yamaguchi in further view of Davidson and in even further view of Lee and in an even further

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view of Herrnstadt et al. and in an even further view of Haygood would have been obvious at the time the invention was made.

Response to Arguments:

In response to applicant's traversal concerning the lack of obviousness over the cited references within the meaning of section 103, as they assert that none of the cited art provides any direction or alternatives in designing primers for the amplification of the target genes in myctophid fishes and furthermore that there is no suggestion in the art for one of ordinary skill to focus on the selected gene regions such as D-Loop(applicant is reminded as an aside that only the D-Loop was elected for further prosecution). The examiner maintains in the above 103 rejection that both a suggestion by the prior art and a motivation to combine the cited references contributed to the obviousness resulting to practice the method as claimed. Specifically, the Haygood reference teaches the claimed genus and species of *Stenobrachius leucopsarus* while the newly cited Paabo reference for example provides a teaching of detecting the mitochondrial regions using the same nucleic acids as primers. The motivation for each combination can be found in the above rejection, but to reiterate just one motivation statement, "PCR techniques make it feasible to target particular gene segments carrying the highest density of intraspecific variation in large numbers of individuals", provides the motivation to detect a gene carrying variation in many individuals.

5. Claims 11, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foran(J. of Exp. Zoology, 1991) in view of Yamaguchi et al.(Molecular Phylogenetics and Evolution, 2000) in further view of Davidson(WO 92/05277), in even further view of Lee et al(J

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Mol. Evol. 1995), in even further view of Herrnstadt et al.(US Patent 5,827,657) and in an even further view of Haygood et al.(J. of Exp. Zoology, 1994) and in an even further view of Paabo et al. (EP0849364A1).

While the teachings of Foran(J. of Exp. Zoology, 1991) in view of Yamaguchi et al.(Molecular Phylogenetics and Evolution, 2000) in further view of Davidson(WO 92/05277), in even further view of Lee et al(J Mol. Evol. 1995), in even further view of Herrnstadt et al.(US Patent 5,827,657) and in an even further view of Haygood et al.(J. of Exp. Zoology, 1994) are summarized above, they do not teach the specific sequences of "CTACC", and SEQ ID NO:4 used as primers to amplify a mitochondrial control region.

However, Paabo et al. do teach SEQ ID NO: 2 to be an oligonucleotide used to amplify the mitochondrial control region, while they further provide the "CTACC" sequence within their sequence of Figure 3A, at positions 27-32, and on pages 3-4, the direction to synthesize primers for their eventual use in the polymerase chain reaction.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the reference of Foran in view of Yamaguchi to analyze the mitochondrial gene of Myctophids and in further view of Davidson and in even further view of Lee and in an even further view of Herrnstadt et al. and in an even further view of Haygood as the reference's teaching of probes to *Stenobrachius leucopsarus* is an addition to the primer sequence teachings of Paabo et al. which provide the means for the advantageous use of this method's ability to "simultaneously potentiate the exponential amplification of molecules of full length and of molecules of truncated length in the reaction which leads to a reduction of the required amount of starting nucleic acid molecules" (Pg. 2 lines 37-40).

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35 U.S.C. 112, Written Description Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 3, 4, 46, 52, 58, 66, 69, and 71 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention

The specification discloses SEQ ID NO: 4, 44, 21, and 22 which corresponds to primers to amplify and detect the D-Loop gene, PSL PROL, and primers for amplifying the PRO-L gene of *Stenobrachius leucopsarus* respectively. Claims 3, 4, 46, 52, 58, 66, 69, and 71 are directed to encompass a method of developing probes from sequences of any gene region in a mitochondrial control gene region, or D-Loop gene from any myctophid fish. The family myctophidae consists of at least 29 classified genera consisting of at least 49 different species. In this large family of myctophidae, a mere 75 nucleotide sequences are indexed on the NCBI database, none of which include a mitochondrial control region of the *Stenobrachius leucopsarus*. The structure of these sequences, probe sequences consisting of fragments, broadly directed to any gene region in a mitochondrial control gene region from any myctophid fish encompass a large genus for which support under the written description requirement is lacking. A review of the full content of the specification indicates that the sequence of these nucleotides and all aforementioned variations, are essential to the operation and function of the claimed invention. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

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<u>Vas-Cath Inc. v. Mahurkar</u>, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See <u>Vas-Cath</u> at page 1116.)

With the exception of SEQ ID NOS: 4, 44, 21, and 22 the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See <u>Fiers v. Revel</u>, 25 USPQ2d 1601, 1606 (CAFC 1993) and <u>Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.</u>, 18 USPQ2d 1016. In <u>Fiddes v. Baird</u>, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, <u>University of California v. Eli Lilly and Co.</u>, 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and

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reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The named ORF is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for isolating and characterizing cDNA sequences from *E. grandis*, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe *E. grandis* cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the specification does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute *E. grandis* cDNA appears in the application. Accordingly, the specification does not provide a written description of the invention of claims 1, 4, and 6-15.

Therefore, none of the sequences encompassed by the claim meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that <u>Vas-Cath</u> makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Allowable Subject Matter

Claim 76 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Sally Sakelaris whose telephone number is (703) 306-0284. The examiner can normally be reached on Monday-Thursday from 7:30AM-5:00PM and Friday from 1:00PM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W.Gary Jones, can be reached on (703)308-1152. The fax number for the Technology Center is (703)305-3014 or (703)305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantae Dessau whose telephone number is (703)605-1237.

Sally Sakelaris

(ally Suh

JEFFREY FREDMAND PRIMARY EXAMINER